

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

208159Orig1s000

OFFICER/EMPLOYEE LIST

NDA 208159 – Vistogard™ (uridine triacetate)

Review Team

The following officers or employees of FDA participated in the decision to approve this application and consented to be identified on this list:

| | |
|--------------------------------------|---------------------|
| Director | Geoffrey Kim |
| Deputy Director | Amna Ibrahim |
| CDTL | Julia Beaver |
| Clinical Reviewer | Gwynn Ison |
| Clinical Pharmacology TL | Qi Liu |
| Clinical Pharmacology Reviewer | Runyan Jin |
| Genomics Reviewer | Sarah Dorff |
| Pharmacometrics Reviewer | Anshu Marathe |
| Non Clinical/Toxicology TL | Todd Palmby |
| Non Clinical/Toxicology Reviewer | David McGuinn |
| CMC Branch Chief | Olen Stephens |
| CMC ATL | Xiao H. Chen |
| Drug substance Reviewer | Xavier Ysern |
| Drug Product Reviewer | Xiao H. Chen |
| Microbiology Process Reviewer - TL | Celia N. Cruz |
| Biopharmaceutics Reviewer | Ge Bai |
| Biopharmaceutics Reviewer | Salaheldin S. Hamed |
| Biopharmaceutics TL | Sandra Suarez-Sharp |
| Associate Director for Labeling | William Pierce |
| OSE/DMEPA/ Medication Error Reviewer | Grace Jones |
| OSE/DRM | Mona Patel |
| DMPP Reviewer | Sharon Mills |
| DMPP Reviewer | LaShawn Griffiths |
| DMPP TL | Barbara Fuller |
| DPMH Pediatric Reviewer | Carol Kasten |
| DPMH Pediatric Reviewer - TL | Hari Sachs |
| OSI TL | Susan Thompson |
| DMEPA Reviewer | Tingting Gao |
| DMEPA Associate Director | Lubna Merchant |
| Chief Project Management Staff | Alice Kacuba |
| Regulatory Project Manager | Jeannette O'Donnell |